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A comparison of the warming capabilities of two Baragwanath Rewarming Appliances with the Hotline® fluid warming device

Dr Kyle Wilson

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology.

Johannesburg, 2021

Declaration

I, Kyle Wilson declare that this research report is my own unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University. With the exception of Section 2 - Draft Article, this document has been formatted according to the Wits University Faculty of Health Sciences style guide. Section 2 - Draft Article, has been formatted according to the South African Journal of Anaesthesiology and Analgesia author guidelines as set out in Section 1 - Author's Guidelines.

The draft article is to be submitted to the journal South African Journal of Anaesthesia and Analgesia for publication.

12 July 2021

Abstract

Background

Accidental intraoperative hypothermia is a common and avoidable adverse event of the perioperative period and is associated with detrimental effects on multiple organ systems and postoperative patient outcomes. In a resource limited environment the prevention of intraoperative hypothermia is often challenging. Resourceful clinicians overcome these challenges through creative devices and frugal innovations. This study aims to investigate the thermal performance of two such Baragwanath Rewarming Appliances (BaRA) against that of the Hotline® in an attempt to describe an optimal setup of these devices.

Methods

This was a quasi-experimental laboratory study that measured the thermal performance of two BaRA devices and the Hotline® in a number of scenarios. Independent variables fluid type, flow rate, warming temperature and warming transit distance were sequentially altered and temperatures measured along the stream of fluid. DeltaT was calculated as the difference between entry and exit temperature for each combination of variables for each warming device.

Results

A total of 219 experiments were performed. The BaRA A configuration at a temperature of 43ºC with a transit distance of 200 cm either matched or exceeded the DeltaT of the Hotline® with all fluid type and flow rate combinations. The BaRA B configuration does not provide comparable thermal performance to the Hotline®. Measured flow rates were noticeably slower than manufacturer quoted values for all intravenous (IV) cannulae used.**Conclusion**

A warm water bath at 43ºC with 200 cm of submerged IV tubing provides thermal performance comparable to the Hotline, with all fluid type and flow rate combinations.

Acknowledgements

I would like to acknowledge the following for their contribution to this research report.

My supervisors, Maria Fourtounas and Christopher Anamourlis, thank you for your guidance and coaching along this academic marathon.

The statisticians from the Health Science Research Office, Dr Innocent Maphosa and Dr Zvifadzo Zingoni and Dr Petra Gaylard from DMSA for making sense of all the 1's and 2's.

Dr Glenda Norman from the Wits University Department of Physiology for granting me access to their lab in order to calibrate the multichannel thermistor.

Mr Thomas Davies for guidance and assistance in the design and construction of the multichannel thermistor and data capture application.

The staff at Chris Hani Baragwanath Academic Hospital for assisting with enduring my makeshift laboratory in JD Allen Theatre 4.

And finally all friends and family that assisted with support both emotional and physical during this MMed.

Abbreviations

ANOVA	Analysis of variance
BaRA	Baragwanath Rewarming Appliance
CEO	Chairperson of the executive office
CHBAH	Chris Hani Baragwanath Academic Hospital
COVID-19	Corona virus disease 2019
CPAP	Continuous positive airway pressure
CSV	Comma separated value
GLM	General linear model
HOD	Head of department
IV	Intravenous
LMICs	Low and middle income countries
MAC	Medical Advisory Committee
NICE	National Institute of Clinical Excellence
PRBC	Packed red blood cells
SANBS	South African National Blood Service
SAJAA	South African Journal of Anaesthesia and Analgesia
SASA	South African Society of Anaesthesiologists
WFSA	World Federation of Societies of Anaesthesiologists
WHO	World Health Organization
Wits	University of the Witwatersrand

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- The submitting/corresponding author is duly authorised to herewith assign copyright to the South African Society of Anaesthesiologists (SASA).
- All co-authors have made significant contributions to the manuscript to qualify as co-authors.
- Ethics committee approval has been obtained for original studies and is clearly stated in the methodology as well as provided as a supplementary file.
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Internet references: World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: World Health Organization, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).

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Section 2. Draft Article

2.1 Cover Letter

Dear Editor

We have included our article entitled “A comparison of the warming capabilities of two Baragwanath Rewarming Appliances with the Hotline® fluid warming device” for your consideration for publication in the South African Journal of Anaesthesiology and Analgesia. Our original piece of research, conducted at Chris Hani Baragwanath Academic Hospital (CHBAH) in Soweto, South African, describes a novel method of warming intravenous (IV) fluids that approximates the performance of a commercially available fluid warming device. This is relevant to the South African perioperative setting where resource limitations often hamper the provision of adequate standards of care.

All authors consent to the publication of the article in the journal and confirm that it has not been published neither is it under peer review elsewhere. The article has been submitted to the University of the Witwatersrand in a research report as part of the requirements for the MMed degree for K Wilson. The authors declare no conflict of interests. All requirements for submission have been obtained including, ethical clearance from the Wits HREC and SANBS as well as permission from the relevant heads of departments of Anaesthesiology at Wits University and CHBAH as well as from CHBAH Medical Advisory Committee. The supporting documents accompany this letter. An article supplement has been included which describes the construction and calibration methods for the data capture device and software used in this study.

Author contributions are as follows. K Wilson conceived the original experiment idea and performed the experiments and data capturing and completed the final writeup. M Fourtounas,

primary supervisor and C Anamourlis, secondary supervisor, provided invaluable guidance on protocol preparation, experiment design, interpretation of results and final document write up.

We look forward to your response

Sincerely

K Wilson	Signed:		Date:	
M Fourtounas	Signed:		Date:	
C Anamourlis	Signed:		Date:	

A comparison of the warming capabilities of two Baragwanath Rewarming Appliances with the Hotline® fluid warming device

K Wilson,[1] M Fourtounas,[1] C Anamourlis[1]

[1]Department of Anaesthesiology, Faculty of Health Sciences, University of the Witwatersrand, South Africa

Corresponding Author, email: rehealthconsulting@gmail.com

Background: Accidental intraoperative hypothermia is a common and avoidable adverse event of the perioperative period and is associated with detrimental effects on multiple organ systems and postoperative patient outcomes. In a resource limited environment the prevention of intraoperative hypothermia is often challenging. Resourceful clinicians overcome these challenges through creative devices and frugal innovations. This study aims to investigate the thermal performance of two such Baragwanath Rewarming Appliances (BaRA) against that of the Hotline® in an attempt to describe an optimal setup of these devices.

Methods: This was a quasi-experimental laboratory study that measured the thermal performance of two BaRA devices and the Hotline® under a number of scenarios. Independent variables fluid type, flow rate, warming temperature and warming transit distance were sequentially altered and temperatures measured along the stream of fluid. DeltaT was calculated as the difference between entry and exit temperature for each combination of variables for each warming device.

Results : A total of 219 experiments were performed. The BaRA A configuration at a temperature of 43ºC with a transit distance of 200 cm either matched or exceeded the DeltaT of the Hotline® over all fluid type and flow rate combinations. The BaRA B configuration does not provide comparable thermal performance to the Hotline®. Measured flow rates were noticeably slower than manufacturer quoted values for all intravenous (IV) cannulae used.

Conclusion: A warm water bath at 43ºC with 200 cm of submerged IV tubing provides thermal performance comparable to the Hotline, with all fluid type and flow rate combinations.

Keywords: perioperative hypothermia, frugal innovation, warming devices

2.2 Introduction

Accidental intraoperative hypothermia, defined as a core temperature below 36ºC, is a common and avoidable adverse event of the perioperative period and is associated with detrimental effects on multiple organ systems and postoperative patient outcomes.[1] Anaesthesia increases the risk of hypothermia by inhibiting the normal homeostatic responses that maintain the body's core temperature. The mechanisms involved in perioperative hypothermia include inhibition of the central and peripheral thermoregulatory responses by the anaesthetic agents used, an increased loss of heat to the environment through patient exposure, administration of cold fluids internally and altered behavioural responses to the cold.[1, 2] Heat loss from the body occurs via five main routes, namely radiation, convection, evaporation, conduction and respiration with loss from radiation accounting for the majority of heat lost. [3]

Anaesthesia is not the only identified risk factor for accidental intraoperative hypothermia. Yi *et al*.[4] conducted a cross sectional study of over 3 000 patients undergoing general anaesthesia in China and found that major surgery, longer duration of surgery (> two hours), un-warmed intravenous (IV) fluids in excess of 1 000 ml and open surgery, were associated with a greater risk of developing perioperative hypothermia. Active warming techniques, higher ambient temperatures and increased patient baseline core temperatures were protective against perioperative hypothermia.[4]

Hypothermia increases the length of stay in the postanaesthetic care unit as well as in hospital and prolongs the recovery from surgery.[5, 6] This is associated with an increase in healthcare costs.[1] In addition, perioperative hypothermia is associated with increased surgical site infections, altered coagulation and altered drug metabolism.[5, 7-9] Shivering is an unpleasant experience and negatively contributes to a patient's perioperative experience.[2] The most serious adverse effects of perioperative hypothermia are related to cardiac complications. Dubick *et al*.[10] propose that hypothermia predisposes the heart to ischaemia as well as reduces the threshold of the myocardium for arrythmias. Frank *et al.*[11] found that by maintaining normothermia there was a reduction in morbid cardiac events perioperatively, which included unstable angina, cardiac arrest, or myocardial ischaemia.

When considering the prevention and management of perioperative hypothermia,

interventions can either be those that minimise heat loss or those that provide active warming.[2] Efforts to minimise heat loss include covering the exposed patient, controlling the environmental temperature and using a heat moisture exchange filter on breathing circuits. Measures that provide active warming can either be provided internally or externally.[12] Internal warming is achieved by providing warmed fluid into either a body cavity or intravenously. Examples of devices that warm the body externally are forced air warmers (3M™ Bair Hugger™), radiant warmers and electric warming blankets.

Various different methods have been described to prewarm IV fluids before administration. These include methods such as storing the fluid in a fluid warming cabinet,[1] prewarming the fluids in a warm water bath[13] or heating the fluid in a microwave[14] before administration. These methods have been shown to be superior at maintaining core temperature compared to administering room temperature fluid and comparable to the performance of commercially available inline fluid warming devices.[1] A disadvantage of prewarming fluids is heat loss to the environment as the fluid is delivered to the patient. The slower the flow rate the greater this effect especially when administering smaller volumes of fluid. Another concern is possible thermal damage to the contents of the fluid if temperatures are too high and the release of toxic substances from the IV fluid bags.[1, 14]

Commercially available devices that actively heat fluid inline while being administered to the patient all rely on a transfer of heat from a heat source to the fluid. The equation

$$\mathbb{Q}/_t = kA\Delta T/_d$$

also known as the thermal conductivity equation, describes the transfer of energy in watts (Q/t) from one object to another as being proportional to the surface area available for heat transfer (A), the temperature difference (ΔT) between the two objects, the thermal conductivity constant (k) specific to the material and the inverse of the distance between the two objects (d).[15]

The effect of these variables on various fluid warming devices has been demonstrated by multiple authors.[13, 16] Thongsukh *et al.*[16] found an inverse relationship between fluid flow rate and thermal performance of a fluid warmer. Schultz *et al.*[13] have described the warming capabilities of different warming methods. A key finding of their study was that a fluid warmer using a temperature controlled coaxial method heated IV fluids more rapidly than

methods that rely on prewarming fluids by placing them in warm water baths or warmed blankets.[13]

Resource-limited settings challenge the delivery of acceptable levels of care with low-and-middle-income countries (LMICs) being the most affected. The resource constraints and environmental limitations of battle zones and austere environments require their devices to be rugged, easy to use, easy to transport, light weight and have minimal power requirements.[10] In these settings, perioperative temperature management often requires creativity on behalf of the healthcare providers for normothermia to be maintained. In response to these constraints a number of creative solutions have been constructed to warm fluids. There are many anecdotal stories of blood products being warmed in warm blankets, buckets of warm water or even in groins and axillae before being administered to patients. Recommendations have been published on the optimal use of these creative solutions. Lindhoff and Palmer [14] describe the optimal use of a microwave for prewarming IV fluids.[14] Shah *et al.*[17] describe a novel fluid warming device using a non-sterile latex glove filled with warmed water to heat a coil of IV fluid being administered to the patient. Craig and colleagues [12] describe a method of prewarming IV fluids using a warm air blower and a modified cooler box.

In 2015 the member states of the United Nations agreed on the Sustainable Development Goals, one of which is Universal Health Coverage by 2030. Part of this coverage includes access to safe, affordable surgical and anaesthetic care. LMICs tend to have the worst access to this level of care.[18] In line with these goals, the Lancet Commission on Global Surgery has identified perioperative care as an area of focus highlighting the necessity to reduce costs, optimise healthcare system and resource usage and improve the delivery of both anaesthetic and surgical care and training.[18] The commission recognises the importance of novel technologies as being key in realising this goal. It is common practice at Chris Hani Baragwanath Academic Hospital (CHBAH) to warm IV fluid by passing the IV tubing through a warm water bath as it flows to the patient. This sort of Baragwanath Rewarming Appliance (BaRA) is an example of a novel technology that addresses this need to provide acceptable anaesthetic care in a resource limited setting.

The concept of frugal innovation has recently emerged and describes innovation that is novel, provides a satisfactory solution and takes place in a resource scarce environment.[19, 20] Weyrauch and Herstatt [20] describe the three criteria for frugal innovation as a significant cost

reduction, concentration on core functionalities and optimised performance level. The BaRA devices are examples of frugal innovation. They are novel IV warming solutions that have emerged due to scarcity of a commercially available alternative. Compared to the Hotline® Blood and Fluid Warmer (Smiths Medical) retailing for approximately R15 000 for the warming unit and R500 for the consumables, these configurations are a fraction of the price. The consumables for a BaRA device will cost approximately R5.75 per 100 cm segment of extension tubing. Both BaRA devices focus on a core functionality of warming fluid without any emphasis on aesthetics, ergonomics or electronic enhancements such as temperature selection. An assessment of the performance of these devices is however, lacking.

The two BaRA configurations used in this study are shown in Figure 1. BaRA A consists of a warm water bath with a variable amount of IV extension tubing submerged in it. BaRA B consists of a variable amount of IV extension tubing wrapped around the tubing of a forced air warmer, Bair Hugger™.

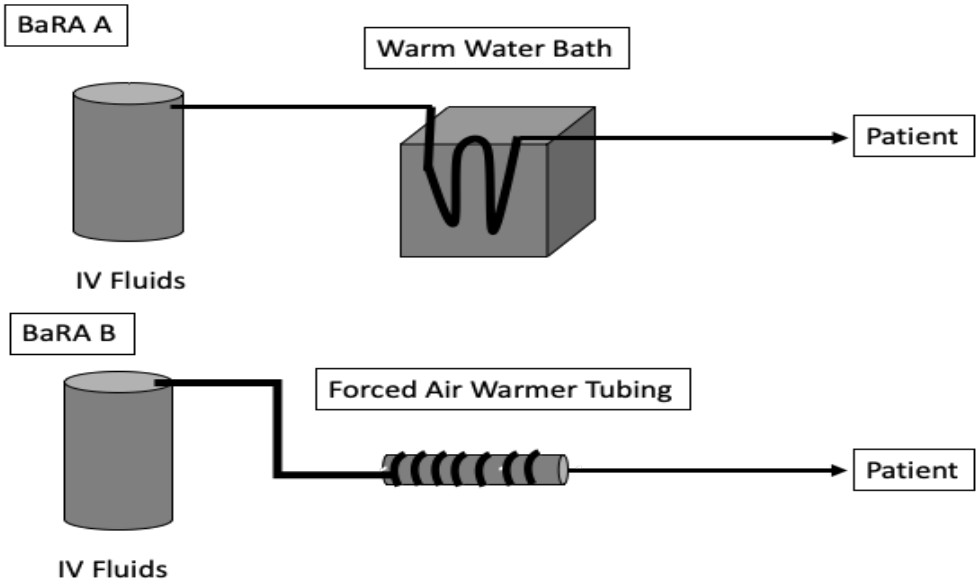
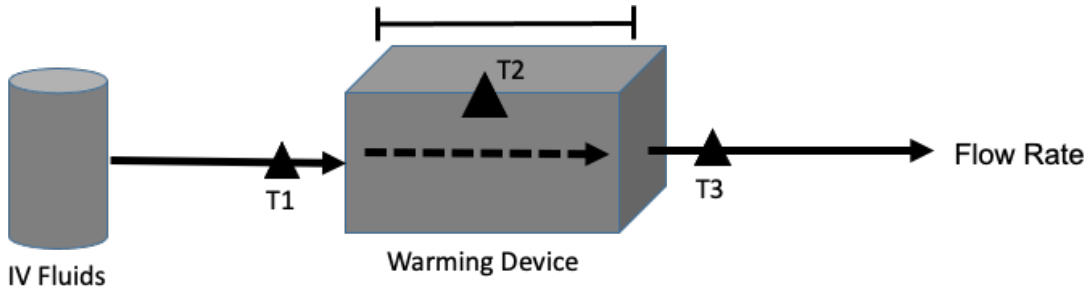


Figure 1 BaRA device configurations

The aim of this study was to describe and compare the warming capabilities of two BaRA devices and the Hotline® device and to describe an optimal assembly of these devices that approximates the warming capabilities of the Hotline®.

2.3 Methods

Ethical clearance from the University of the Witwatersrand Human Research Ethics Committee (Medical) (M2008107), as well as permission to use human blood products granted from the South African National Blood Services (2019/0520) were obtained prior to commencing the study A quasi-experimental, quantitative research design was employed for this study.. The study was conducted in an unused, fully operational surgical theatre at CHBAH using standardised 20 drops/min IV and 10 drop/min blood administration sets and IV cannulae. Dextrose water was included in the study as an electrolyte free control fluid. Ambient air temperature and fluid temperatures were continuously monitored for fluctuations during the experiments. Under experimental conditions, independent variables relating to the Hotline®, BaRA A and BaRA B were sequentially altered in order to assess the effect on temperature at points T1 and T3, the dependent variables. Figure 2 illustrates the experiment



Independent Variable	Holtine® Independent Variables	Baragwanath Rewarming Appliance (BaRA) – Independent Variables	
		BaRA A	BaRA B
IV Fluids	• Dextrose Water – Room Temperature • Packed red blood cells– Refrigerated • Ringers Lactate - Room Temperature • Voluven - Room Temperature		
Flow Rate	• 22G Cannula – 36mL/min • 20G Cannula – 60mL/min • 18G Cannula – 100mL/min		
Warming Device Temperature	• Manufacturer Determined	• 38°C • 43°C	• 38°C • 43°C
Warming Transit Distance	• Manufacturer Determined	• 100cm • 200cm	• 100cm • 200cm

Figure 2 Experiment schematic

setup, the independent variables related to each warming device and the location of the temperature measurement points.

Fluid flow rates were determined via a gravity delivery method through 3 different sized IV cannula, 18G, 20G and 22G. This was done in order to mimic a clinical scenario. IV fluids were kept at a standard 1 m height above the warming device to control driving pressure and the IV cannula changed to modify resistance to flow. Actual fluid flow rates were measured for each combination of independent variables through each IV cannula,

The independent variables for each BaRA configuration were assigned a code which described the warming device configuration e.g. Ba.43.200. Table 1 outlines this coding system. Twelve combinations of independent variables for the Hotline® and 48 combinations for each BaRA configuration were tested totalling 108 experiment combinations.

Table 1 Experiment coding key

Code	Interpretation
Ba	BaRA A configuration
Bb	BaRA B configuration
38	38ºC - Warming device temperature
43	43ºC - Warming device temperature
100	100 cm – transit distance
200	200 cm – transit distance

Temperature was recorded at six points and stored by a multichannel thermistor and data capture software (BaRAGRABA 2.0), both specifically designed for this experiment. Full details on device and software construction and calibration are available in Appendix F. In-stream temperatures were recorded at T1 and T3. T2 was monitored in order to maintain warming device temperature for BaRA A experiments. This was achieved by the addition of warm water to the bath to maintain the target temperature. Hotline® and BaRA B temperatures were determined by the individual devices. Ambient temperature and inline fluid

temperature at two distal points were also recorded and monitored in order to control experiment conditions.

Temperature measurements were recorded automatically at 500 ms intervals for a period equal to the transit period plus five seconds. The transit period was calculated as the time taken for a bubble indicator to travel from T1 to T3. These temperature measurements were automatically measured and saved digitally. The warming capabilities of the device, DeltaT, was determined as the difference between the mean exit temperature at T3 and the mean entry temperature at T1.

Data analysis was carried out using SAS v9.4 for Windows. A 5% significance level was used. Each dependent variable, for each warming device, was modelled in terms of the relevant independent variables and their two-way interactions using a General Linear Model (GLM). Outliers were removed as indicated by model diagnostics. Non-significant interaction terms were removed for model parsimony. Comparison of each dependent variable at a given combination of fluid type and flow rate for the Hotline® to that of the eight corresponding BaRA A and BaRA B device conditions was done using a one-way ANOVA. Post-hoc tests were conducted using the Tukey-Kramer adjustment for unequal group sizes to determine which BaRA A and BaRA B combinations did not differ significantly from the Hotline®.

2.4 Results

Experiments were conducted twice at each combination of independent variables, giving a total of 216 experiments. Data for nine experiments were missing due to file errors. Figure 3 shows the estimated mean DeltaT of the warming devices at each combination of independent variable. The whiskers indicate the 95% confidence interval.

Table 2 shows the BaRA combinations, marked in black, where DeltaT matched or exceeded the Hotline®

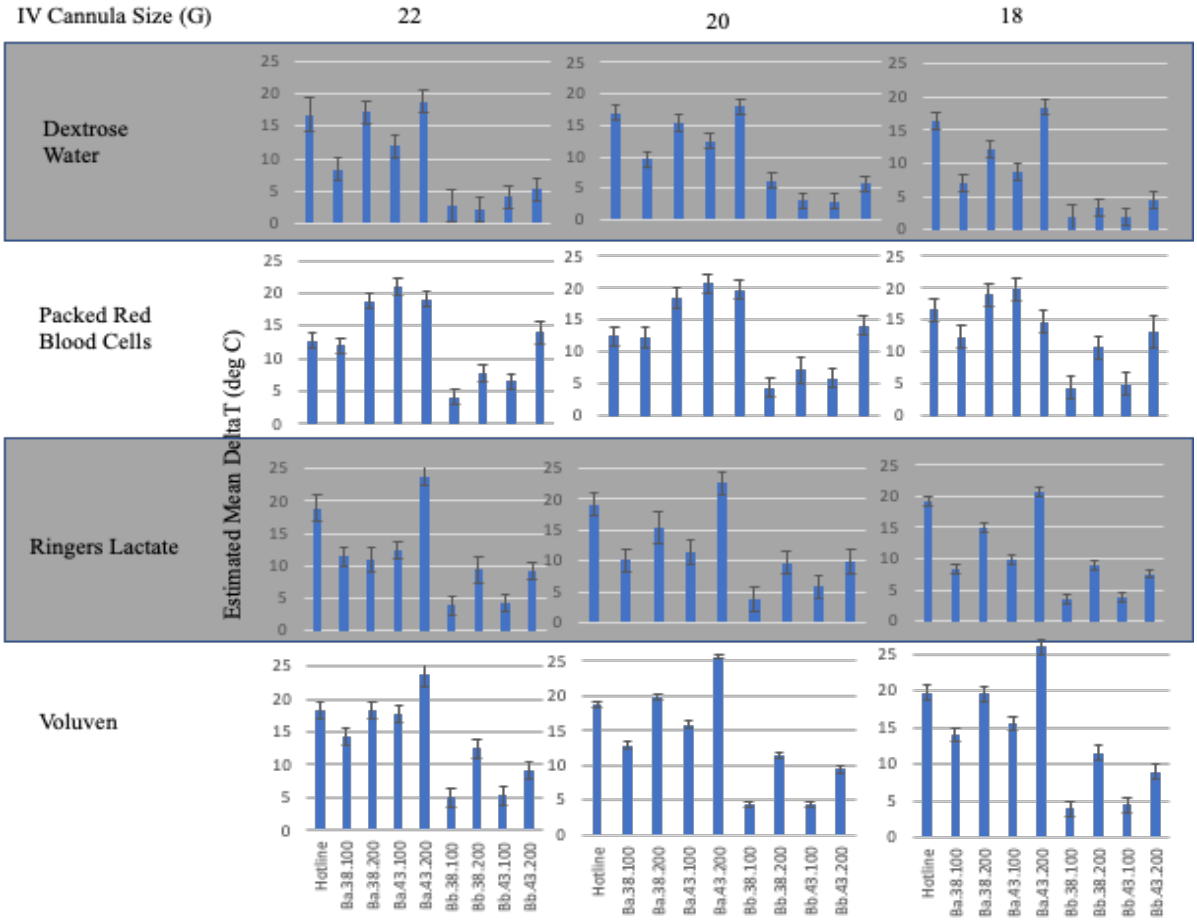


Figure 3 Estimated mean DeltaT for each warming device

Table 2 BaRA configurations that matched or exceeded the Hotline® for DeltaT (marked in black)

	Dextrose Water			Packed Red Blood Cells			Ringers Lactate			Voluven®		
IV Cannula Size (G)	**22**	**20**	**18**	**22**	**20**	**18**	**22**	**20**	**18**	**22**	**20**	**18**
Ba.38.100				■	■	■						
Ba.38.200	■	■		■	■	■		■		■	■	■
Ba.43.100	■			■	■	■				■		
Ba.43.200	■	■	■	■	■	■	■	■	■	■	■	■
Bb.38.100												
Bb.38.200												
Bb.43.100												
Bb.43.200				■	■	■						

Ba.43.200 was the only configuration that provided a similar DeltaT to the Hotline® under all fluid and flow rate combinations. Other BaRA A configurations provided comparable DeltaT values but only under specific fluid and flow rate combinations. When packed red blood cells (PRBC) were utilised all configurations of BaRA A had a similar DeltaT to the Hotline®.

The BaRA B devices only approximated the DeltaT of the Hotline® in the Bb.43.200 configuration and only when PRBC were used. No other combination of variables of this device approximated the Hotline® DeltaT.

Table 3 shows the measured flow rates for each fluid through each warming device. Of note, there is a large difference between the manufacturer stated flow rates and the measured flow rates for each cannula. Flow rates between fluids also varied, substantially in the case of PRBC. PRBC and Voluven® had the lowest flow rates of all fluids through all devices and at all flow rates. PRBC had notably lower flow rates through the Hotline® at all flow rates.

Table 3 Measured flow rates of IV cannulae (ml/min)

IV Cannula Size (G)	**22**			**20**			**18**		
Device*	**Hotline®**	**BaRA A**	**BaRA B**	Hotline®	**BaRA A**	**BaRA B**	**Hotline®**	**BaRA A**	**BaRA B**
Dextrose Water	18	19,5	19,5	24	26,25	24	33	36	33
Packed Blood Red Cells	3	6	6	3,99	15	15	4,5	16,5	16,5
Ringers Lactate	24	18	15	34,5	21	21	43,5	27	24
Voluven®	11,1	7,5	6	14,25	9	11,25	16,5	16,5	15

* BaRA devices had the same measured flow rates for both 100 and 200 cm transit distances.

2.5 Discussion

The aim of this study was to describe and compare the warming capabilities of two BaRA devices and the Hotline® in an attempt to describe a configuration of the BaRA device that would best approximate the warming capabilities of the Hotline®. Table 2 illustrates that if we want a one-combination-fits-all match for the thermal performance of the Hotline®, it would

be Ba.43.200. This is the BaRA A configuration with a warming temperature of 43ºC and a transit distance of 200 cm. There are a number of isolated conditions for the BaRA A configuration that approximates the Hotline® but only under specific fluid and flow rate combinations. The BaRA B configuration , under most fluid type and flow rate combinations, does not provide a comparable amount of heating compared to the Hotline®. Only under the specific condition, Bb.43.200 with PRBC, is the performance similar.

The transfer of heat energy from the warming device to the fluid is proportional to the surface area available for heat transfer. The entire surface area of the extension tubing is included in heat transfer in both the Hotline® and BaRA A devices as it is either enveloped or submerged by the warming device. This superior warming effect by a coaxial system has been previously describe in a study by Shultz *et al*.[13] The BaRA B device has only a fraction of the tubing surface area in contact with the warming device as it is coiled on the outer surface of the Bair Hugger™ warmer conduit.

Fluid transit time is a function of the fluid flow rate and transit distance. Longer transit times allow for greater heating of the fluid. Thongsukh *et al.*[16] have previously shown the inverse relationship between flow rate and warming device performance. Interestingly the measured flows were only approximately 5 – 55% of manufacturer quoted flows. Measured fluid flow rates were much higher with less viscous fluids, dextrose water and Ringers Lactate, and decreased as viscosity increased, PRBC and Voluven®. The significance of this is that more viscous fluids had longer transit times and resultant increased heating. This may explain why PRBC were better heated compared to the other fluids under both BaRA A and B configurations. It is notable that the PRBC flowed slower through the Hotline® than the other two devices. Thermistors were mounted within the flow of fluids and may have also affected flow rates. These factors are important considerations when interpreting the results of this study. At higher flow rates, the conclusion of this study may no longer be valid.

In clinical practice, cooling of the fluid will occur as soon as the fluid leaves the warming device, which depends on the same factors as those that affect heat gain. BaRA A and BaRA B would require a significant length of IV tubing outside the warming device in order to connect the patient to the warmed fluids. It is possible with the Hotline® to connect the warmed fluids directly to the patient reducing heat loss significantly.

There were a number of technical challenges with the conduct of the study. Firstly, the study was quasi-experimental as no randomisation was performed. This potentially allows repeat error to bias a particular experiment condition. The reason for this design was to make efficient use of resources, time and PRBC being the most important. Secondly, it was not anticipated that the electrolyte solutions would alter the readings of the thermistors. This was indeed the case and the thermistor leads required insulation and recalibration. Dextrose water was included in the study as a control for the effects of the electrolytes on the thermistors. After insulation there were comparable readings at all temperature points with all fluids.

The use of an analogue electronic system, such as the multichannel thermistor, poses a number of challenges. As the system increases in complexity, and more thermistors are added, electrical interference within the system increases and calibration becomes more difficult and less reliable. The effect of this may only be on measuring absolute temperatures which are indirectly calculated through the Steinhart-Hart equation. The relative changes between temperatures, such as the DeltaT, should not be affected as the relationship between temperature and resistance remains fixed within the system. Should the study be repeated digital temperature monitoring would be an ideal upgrade. Finally, the BaRAGRABA 2.0 corrupted 9 out of the 216 data sets. Despite this loss there were a large number of data points available for statistical comparison.

The use of the BaRA A and B configuration is not unique to CHBAH. The use of these configurations are described in many other resource limited settings as clinicians attempt to provide the best care to the patients. This illustrates the power of frugal innovation in addressing a far reaching clinical problem.

2.6 Conclusion

Despite the challenges, the findings of the study provide valuable insight into the use of the BaRA devices as alternatives to the Hotline®. To the knowledge of the authors this is the first study that compares the warming capabilities of the Hotline® with the BaRA devices. Resource limited settings challenge the provision of adequate levels of perioperative care. Perioperative hypothermia is a preventable complication during anaesthesia with the provision of adequately warmed IV fluids forming a major part of this prevention. We describe a method of constructing a fluid warming device out of commonly available theatre

consumables, the BaRA A, that approximates the warming capabilities of the Hotline®. This configuration should provide warming of dextrose water, Ringers Lactate, packed red blood cells and Voluven® through IV cannula of sizes 22G, 20G and 18G that is comparable to the Hotline®. The challenges outlined in the study may assist in the future design of a similar study. The results will guide replication of the BaRA devices for effective clinical use.

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Declaration of conflict of interest

The authors have no conflict of interest to declare.

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Ethics declaration

Ethical clearance was obtained prior to commencing the study from the Wits Human Research Ethics Committee (Medical) (M2008107) as well as permission to use human blood products granted from the South African National Blood Services (2019/0520).

ORCID

K Wilson https://orcid.org/0000-0002-4887-9531

M Fourtounas https://orcid.org/0000-0002-3678-018X

C Anamourlis https://orcid.org/0000-0001-5509-2473

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Section 3. Proposal

3.1 Extended Literature Review

Accidental intraoperative hypothermia, defined as a core temperature below 36ºC, is a common and avoidable adverse event of the perioperative period and is associated with detrimental effects on multiple organ systems and postoperative patient outcomes[1]. Anaesthesia increases the risk of hypothermia by inhibiting the normal homeostatic responses that maintain the body's core temperature. The mechanisms involved in perioperative hypothermia include inhibition of the central and peripheral thermoregulatory responses by the anaesthetic agents used, an increased loss of heat to the environment through patient exposure, administration of cold fluids internally and altered behavioural responses to the cold[1, 2]. Heat loss from the body occurs via five main routes, namely radiation, convection, evaporation, conduction and respiration with loss from radiation accounting for the majority of heat lost[3].

Anaesthesia is not the only identified risk factor for accidental intraoperative hypothermia. Yi *et al.*[4] conducted a cross sectional study of over 3 000 patients undergoing general anaesthesia in China and found that major surgery, longer duration of surgery (> two hours), un-warmed intravenous (IV) fluids in excess of 1 000 ml and open surgery were associated with a greater risk of developing perioperative hypothermia. Active warming techniques, higher ambient temperatures and increased patient baseline core temperatures were protective against perioperative hypothermia.

Hypothermia increases the length of stay in the post-anaesthetic care unit as well as in hospital and prolongs the recovery from surgery[5, 6]. This is associated with an increase in healthcare costs[1]. In addition, perioperative hypothermia is associated with increased surgical site infections, altered coagulation and altered drug metabolism[5, 7-9]. Shivering is an unpleasant experience and negatively contributes to a patient's perioperative experience[2]. The most serious adverse effects of perioperative hypothermia are related to cardiac complications. Dubick *et al.*[10] propose that hypothermia predisposes the heart to ischaemia as well as reduces the threshold of the myocardium for arrythmias. Frank *et al.*[11] found that by maintaining normothermia there was a reduction in morbid cardiac events perioperatively which include unstable angina, cardiac arrest, or myocardial ischaemia.

Considering these consequences as well as the incidence of hypothermia, which ranges from 20 – 44.3% [2, 6], it is not surprising that the maintenance of normothermia is a specific perioperative goal. The importance of this is reflected in a number of international guidelines outlining the minimum level of care regarding perioperative hypothermia. The overarching aims of these guidelines are to guide best practice and ensure patient safety.

The South African Society of Anaesthesiologists (SASA), in their 2018 practice guidelines [12], have acknowledged the importance of perioperative temperature management with specific mention being made to the need to monitor patient temperature for procedures planned to take longer than 30 minutes, as well as active measures required to maintain a core temperature of between 36 and 37ºC. A thermometer and a blood or fluid warmer are listed as essential items of equipment that should be available at all hospital levels, failing which the provision of an anaesthetic becomes unsafe[12].

The National Institute of Clinical Excellence (NICE) [13] published guidelines in 2008 on the prevention and management of hypothermia in adults undergoing surgery. The guidelines describe strategies during the preoperative, intraoperative and postoperative periods for the identification, prevention and management of hypothermia. A key aspect of the intraoperative strategies is the use of a forced air warmer as well as warming all IV fluids to 37 ºC and all irrigation fluids to between 38 – 40 ºC before administering to the patient[13].

The Safetots Initiative [14] addresses the provision of safe anaesthesia to children and has developed the 10-N principle as a set of clinical goals to achieve during paediatric anaesthesia. Normothermia is listed (along with normal heart rate, blood pressure and normoxaemia) as one of the goals. The paediatric population is especially sensitive to changes in body temperature and the deleterious effects of hypothermia[14].

In 2018 the World Health Organization (WHO) and World Federation of Societies of Anaesthesiologists (WFSA) published recommendations for the international standards for the safe practice of anaesthesia[15]. In the recommendations, both intermittent temperature monitoring and the availability of a device for warming IV fluids and blood are recommended standards during perioperative care. A recommended standard, in this case, is one that should be practiced when resources allow and if appropriate for the clinical scenario, while a highly recommended standard is the minimum expected standard for the provision of a safe

anaesthetic[15]. Temperature monitoring and management devices do not feature on the highly recommended list of standards. This is in contrast to the SASA and NICE guidelines which place a greater emphasis on the importance of temperature management. The reason for this contrast is possibly an attempt to cater for the varied level of resources available on a global level.

When considering the prevention and management of perioperative hypothermia, interventions can either be those that minimise heat loss or those that provide active warming[2]. Efforts to minimise heat loss include covering the exposed patient, controlling the environmental temperature and using a heat moisture exchange filter on breathing circuits. Measures that provide active warming can either be provided internally or externally[16]. Internal warming is achieved by providing warmed fluid into either a body cavity or intravenously. Examples of devices that warm the body externally are forced air warmers, radiant warmers and electric warming blankets.

It is commonly quoted that infusing one litre of room temperature (21 ºC) fluid into an adult will reduce the core body temperature by 0.25ºC[17, 18]. Sixteen kilocalories of energy are needed to warm this litre from room temperature to a core body temperature of 37ºC[19]. Shivering is the principle mechanism by which the body generates this energy. By preheating the fluid to core body temperature the requirement to generate this extra energy no longer falls on the body's metabolism. The narrower the temperature gradient between the body and the infused fluids, the less the additional energy requirements to heat the fluid and conversely the smaller the change in body temperature[20].

Various methods have been described to prewarm fluids before administration. These include methods such as storing the fluid in a fluid warming cabinet[1], prewarming the fluids in a warm water bath[20] or heating the fluid in a microwave[21] before administration. These methods have been shown to be superior at maintaining core temperature compared to administering room temperature fluid and comparable to the performance of commercially available inline fluid warming devices[1]. A disadvantage of prewarming fluids is heat loss to the environment as the fluid is delivered to the patient. The slower the flow rate the greater this effect especially when administering smaller volumes of fluid. Another concern is possible thermal damage to the contents of the fluid if temperatures are too high and the release of toxic substances from the IV fluid bags [1, 21].

Commercially available devices that actively heat fluid inline while being administered to the patient all rely on a transfer of heat from a heat source to the fluid as it flows past the heat source. The equation

$$\mathbb{Q}/_t = kA\Delta T/_d$$

also known as the thermal conductivity equation, describes the transfer of energy in watts (Q/t) from one object to another as being proportional to the surface area available for heat transfer (A), the temperature difference (ΔT) between the two objects, the thermal conductivity constant (k) specific to the material and the inverse of the distance between the two objects (d)[22]. As an example, the commercially available Hotline® Blood and Fluid Warmer (Smiths Medical) uses a coaxial system to maintain a temperature difference between the warmer and the IV fluid while providing a large surface area for heat transfer.

The effect of these variables on various fluid warming devices has been demonstrated by multiple authors. Thongsukh *et al.*[18], found an inverse relationship between fluid flow rate and thermal performance of a fluid warmer. Schultz *et al.*[20] have described the warming capabilities of different warming methods. A key finding of their study was that a fluid warmer using a temperature controlled coaxial method heated IV fluids more rapidly than methods that rely on prewarming fluids by placing them in warm water baths or warmed blankets[20].

Resource-limited settings challenge the delivery of acceptable levels of care with low-and-middle-income-countries (LMICs) being the most affected. Battle zones and austere environments are also subject to resource constraints and require their devices to be rugged, easy to use, easy to transport, light weight and with minimal power requirements[10]. Perioperative temperature management often requires creativity on behalf of the healthcare providers for normothermia to be maintained. In response to these constraints a number of creative solutions have been constructed to warm fluids. There are many anecdotal stories of blood products being warmed in warm blankets, buckets of warm water or even in groins and axillae before being administered to patients. Recommendations have been published on the optimal use of these creative solutions. Lindhoff and Palmer [21] describe the optimal use of a microwave for prewarming IV fluids[21]. Shah *et al.*[23] describe a novel fluid warming device using a non-sterile latex glove filled with warmed water to heat a coil of IV fluid being

administered to the patient. Craig and colleagues [16] describe a method of prewarming IV fluids using a warm air blower and a modified cooler box.

In 2015 the member states of the United Nations agreed on the Sustainable Development Goals, one of which is Universal Health Coverage by 2030. Part of this universal coverage is access to safe, affordable surgical and anaesthetic care. LMICs tend to have the worst access to this level of care[24]. In line with these goals, the Lancet Commission on Global Surgery has identified perioperative care as an area of focus highlighting the necessity to reduce costs, optimise healthcare systems and resource usage and improve the delivery of both anaesthetic and surgical care and training. The commission recognises the importance of novel technologies as being key in realising this goal. It is common practice at Chris Hani Baragwanath Academic Hospital (CHBAH) to warm IV fluid by passing the IV tubing through a warm water bath as it flows to the patient. This sort of Baragwanath Rewarming Appliance (BaRA) is an example of a novel device that, through the process of frugal innovation, addresses this need to provide acceptable anaesthetic care in a resource limited setting.

The concept of frugal innovation has recently emerged and describes innovation that is novel, provides a satisfactory solution and takes place in a resource scarce environment[25, 26]. In a review on the patterns of frugal innovation in healthcare published in 2018, Arshad *et al.* [27] noted that the majority of these innovations originated in industrialised countries with target markets in Africa and Asia. Most developers were either multinational corporations or grass root entrepreneurs creating products for general practice, neonatology and orthopaedics. The current COVID-19 pandemic has provided an environment favouring frugal innovation with a number of solutions targeting respiratory hygiene and support being developed. The Bousssignac CPAP ventilator, a cheap, easy to set up and non-electric ventilator is an example of such a development. The frugal approach may allow the provision of better levels of care to critically ill patients in resource limited settings with some authors calling for further research into frugal developments in the area of critical care[28]. While makeshift solutions are no replacement for gold standards, they do bridge the economic gap between scarcity and abundance.

3.2 Problem Statement

Intraoperative hypothermia is a well described phenomenon associated with various complications. The prevention and treatment both rely on preventing heat loss and actively warming the patient. Providing warmed IV fluids is one method of achieving this. Commercially available fluid warming devices are often not available in resource scarce medical facilities and patients are exposed to fluids that have been inappropriately warmed. Overwarming has the potential to damage the IV fluid as well as packaging, while under warming exposes the patient to the risks of hypothermia. Due to scarcity, CHBAH perioperative healthcare providers often have to rely on make shift IV warming devices. There are no standards set for these devices and thermal performance is presumably haphazard. No studies were found that compare the performance of the BaRA configuration with a commercially available device.

3.3 Aim

The aim of this study is to describe and compare the warming capabilities of two BaRA devices and the Hotline® device and to describe an optimal assembly of these devices that approximates the warming capabilities of the Hotline®.

3.4 Objectives

The primary objectives of this study are to :

- determine the warming capabilities of the Hotline® by manipulating the following independent variables
    - fluid type
    - fluid flow rate
- determine the warming capabilities of two BaRA devices by manipulating the following independent variables
    - fluid type
    - fluid flow rate
    - warming device temperature
    - warming transit distance

- compare the warming capabilities of the Hotline® with those of the BaRA devices

The secondary objective of the study is to:

- describe an assembly of the BaRA devices that best approximates the warming capabilities of the Hotline®

3.5 Research assumptions

BaRA configurations – Fluid warming devices constructed from items easily available in the operating theatres at CHBAH.

BaRA A – A BaRA configuration using a variable length of IV tubing immersed in a warm water bath as the warming device (Figure. 3-1).

BaRA B – A BaRA configuration using a length of IV tubing coiled around the hose of a forced air warmer as the warming device (Figure. 3-1).

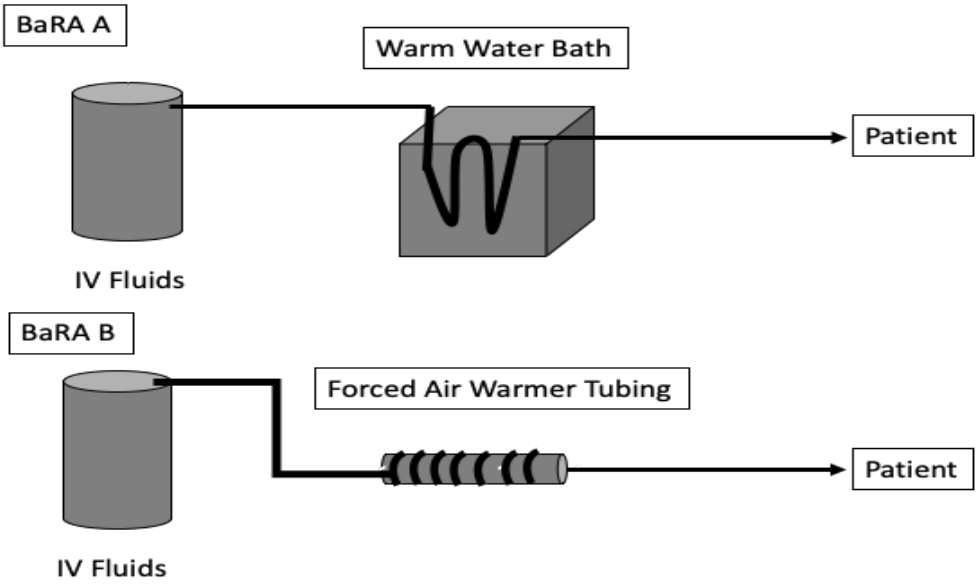


Figure 3-1 BaRA device configurations

Independent variables – Variables that will be systematically altered to determine their effects on the dependent variable, temperature. For this study there are two groups of independent variables, namely clinical scenario variables and BaRA variables.

Clinical scenario – A combination of fluid type and flow rate that simulates commonly encountered fluid administration scenarios in the operating theatre environment.

Clinical scenario variables – variables that will be sequentially adjusted in order to recreate a group of nine commonly encountered fluid administration scenarios. These include fluid type, temperature and flow rate (Figure.3-2).

Fluid type – one of two variables used to simulate the clinical scenarios mentioned above. The fluid types are selected from either of three commonly used IV fluids, namely Ringers Lactate, Voluven® and packed red blood cells (PRBC).

Ringers Lactate – a balanced crystalloid fluid

Voluven® - a colloid in normal saline solution manufactured by Fresenius-Kabi

Packed Red Blood Cells (PRBC)– packed red blood cells processed by the South African National Blood Service (SANBS).

Flow rate – The second of the clinical scenario variables is the flow rate of the fluid through the IV cannula controlled by either of three IV cannulae commonly found in theatre (22G, 20G and 18G). These provide manufacturer quoted flow rates of 35, 60 and 100ml/min respectively.

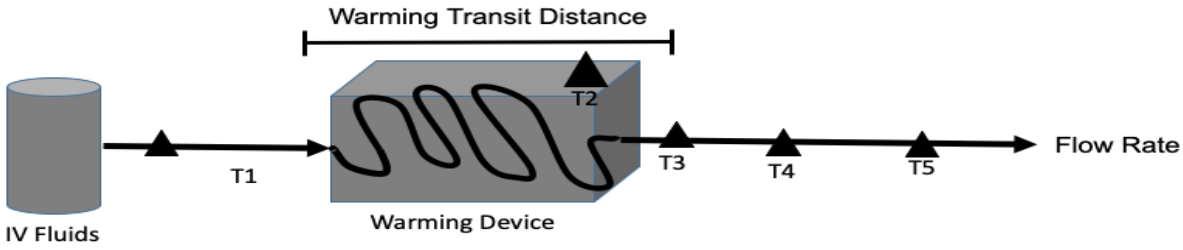
Fluid temperature – Ringers Lactate and Voluven® are both normally stored at room temperature (21 ºC), while PRBC are stored refrigerated at a temperature of 4 ºC.

BaRA variables - variables that will be sequentially adjusted to test the performance of each BaRA device and include warming distance and warming device temperature (Figure.3-2).

Warming distance – The length of IV tubing exposed to the warming medium. Two lengths of commonly available extension tubing will be used; 100 and 200 cm.

Warming device temperature – The warming device temperatures will be controlled to either 37 or 43 ºC.

Dependent variables - temperatures measured at points T3, T4, T5 (Figure.3-2)



Clinical Scenario Variables			Baragwanath Rewarming Appliance (BaRA) Variables		
	IV Fluids	Flow Rate		Warming Device Temperature	Warming Transit Distance
Variable	• Ringers Lactate - Room Temperature • Voluven - Room Temperature • Red Cell Concentrate - Refrigerated	• 22G Cannula – 36mL/min • 20G Cannula – 60mL/min • 18G Cannula – 100L/min	Variable	• 37°C • 43°C	• 100cm • 200cm

Figure 3-2 Experiment schematic

Temperature points (Figure 2)

T1 – The fluid temperature measured within 10cm of entering the warming device.

T2 – The warming device temperature.

T3 – The fluid temperature measured within 10cm of exiting the warming device.

T4 – The fluid temperature measured at 100 cm after exiting the warming device.

T5 – The fluid temperature measured at 200 cm after exiting the warming device.

T6 – Ambient room temperature.

Multichannel thermistor – This multichannel digital thermometer consists of five 10K ohm glass bead thermistors (DHT0B103J3953SY Communica Electronics) mounted in three way stop-cocks which allows the in-stream measurement of fluid temperature. The device was specifically constructed for this experiment and is used in conjunction with the BaRAGRABA 2.0 application.

Steinhart-Hart Equation – The relationship between temperature and resistance measured in a thermistor is not linear. Steinhart and Hart[29] formulated an equation that best describes this relationship which is used to convert a measured resistance to a corresponding temperature. The equation is $T^{-1} = A + B \log R + C (\log R)^3$ and contains the variables temperature in

Kelvin (T), resistance (R) and three coefficients A, B and C. The coefficients can be used to calibrate the thermistor.

3.6 Demarcation of the study field

The study will be conducted in an unused, fully operational surgical theatre at CHBAH. It is a central hospital consisting of 2888 beds, 25 main theatres and conducts approximately 65 000 surgical cases annually. The Department of Anaesthesiology at CHBAH is affiliated to University of the Witwatersrand (Wits).

3.7 Ethical considerations

No human subject will participate in the study. Human tissue will be used, in the form of PRBC and an application for ethical clearance will be submitted to the Wits Human Research Ethics Committee (Medical). Coordination will take place between the principal investigator and the CHBAH theatre management in order to prevent the study from interfering with the provision of normal surgical services at the hospital.

Preapproval from SANBS has been granted for the use of blood products (Appendix A). A formal application will be submitted online to the SANBS once approval of the study is granted by the Postgraduate Research Committee. Approval to complete the study will be obtained from both the heads of the Departments of Anaesthesiology at Wits and CHBAH as well as the Medical Advisory Committee and CEO of CHBAH (Appendix B).

The study will be conducted according to the principles of the Declaration of Helsinki[30] and the South African Guidelines for Good Clinical Practice[31].

3.8 Research methodology

3.8.1 Research design

According to Last [32] an experimental study is one in which “study conditions are under the direct control of the investigator”. An important distinction is made between the randomised experiment and a quasi-experiment. The critical difference is the process of random assignment to control or intervention groups in a randomised experiment and the lack of this

process in a quasi-experiment[33]. Quantitative research focuses on the collection of objective data and the analysis of this data using statistical and mathematical methods[34].

This research design is a quasi-experimental, quantitative study. Under experimental conditions, the independent variables will be sequentially altered in order to assess the effect on temperature, the dependent variable. There will be no randomisation to experiment groups. Statistical analysis will be performed on the temperatures measured.

As outlined in the aims and objectives of the study, the thermal performance of the BaRA devices will be compared to the those of the Hotline® in an attempt to describe a BaRA configuration that best approximates the performance of the Hotline®.

These objectives will be achieved as follows.

Firstly, the warming performance of the Hotline® will be tested. Nine clinical scenarios will be simulated and temperature measured at points T1 - T5 (Figure. 2). These nine clinical scenarios will be created by combining the fluid type and flow rates. The fluids used will be Ringers Lactate and Voluven® at room temperature (21 ºC) and packed red blood cells at fridge temperature (4 ºC). Fluid flow rate will be controlled and standardised by using size 22G (36 ml/min), 20G (60 ml/min) and 18G (100 ml/min) IV cannulae.

Following the process above, the nine clinical scenarios will be recreated for each of the BaRA devices. In addition, the BaRA variables, warming device temperature at either 37 or 43 ºC and warming transit distance at either 100 or 200 cm, will be altered sequentially and temperatures at T1 - T5 measured for each combination.

3.8.2 Study sample

Sample size

A total of 162 experiments will be performed (Figure 3-3.). Nine experiments will be completed with the Hotline® and will comprise the clinical scenarios. A further 36 experiments will be conducted for both the BaRA A and B devices. These 36 experiments will be the nine clinical scenarios with sequential adjustment of each BaRA variable. Each experiment will be completed twice in order to obtain an average temperature value for comparison.

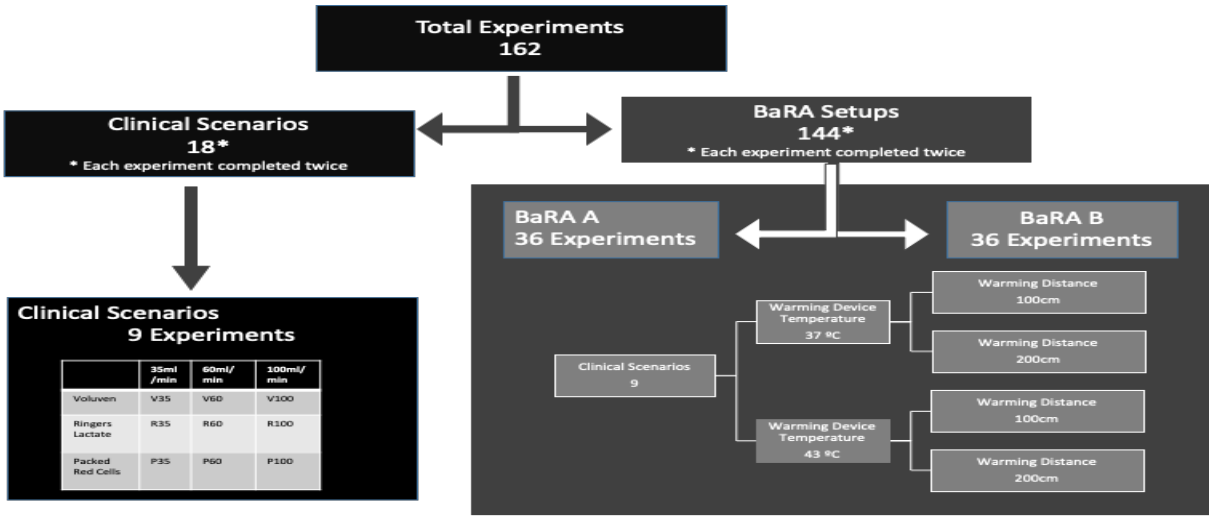


Figure 3-3 Sample population

Sample method

All experiments will be included in the study. Initially the clinical scenarios using the Hotline® will be created. This will follow a systematic approach starting with Voluven® at each flow rate and then progressing to Ringers Lactate and then PRBC. Once the performance of the Hotline® has been recorded under the nine clinical scenarios they will be recreated for each BaRA configuration in the same order as for the Hotline®. For each clinical scenario, the

warmer temperature and warming distance will be sequentially adjusted.

3.8.3 Collection of data

The multichannel thermistor and data capture application will be constructed specifically for this experiment. This process will take place in consultation with an independent electrical engineer and the Wits School of Electrical and Information Engineering. Calibration of the device will take place at the Wits School of Physiology using a standardised thermometer for reference temperature measurements. The complete construction and calibration process is further discussed in Appendix F – Multichannel Thermistor Construction and Calibration.

Temperature monitoring thermistor probes will be secured into modified 3-way Luer stopcocks and placed inline to the flow of fluid at positions T1, T3, T4 and T5 (Figure 2). A thermistor probe will be secured into the warming device at T2.

The experiment will be setup as shown in Figure 2. A bubble indicator will be introduced into the system at T1. The tap on the IV tubing will be opened and once the bubble has reached the end of the IV tubing, downstream to T5, the temperature recording will begin. The time taken for the bubble to travel between T1 and T5 will be recorded as the transit period. Temperature measurements will be recorded automatically at 500ms intervals for a period equal to the transit period plus five seconds. These measurements will be automatically measured and saved digitally in comma-separated value (CSV) format by the multichannel thermistor.

Each experiment will receive a unique code that will describe the experiment conditions. The first portion of the code describes the warming device e.g. Ba – BaRA A, Bb – BaRA B. The second portion of this code describes the fluid type and flow rate of the clinical scenario e.g. V35 – Voluven® at 35 ml/min. The third portion of the code describes warming device temperature and warming distance of the BaRA devices. E.g. 37.100 – temperature of 37 ºC for a distance of 100 cm. An example of this code is as follows Ba.V35.37.100. This describes the BaRA A device using Voluven® at a flow rate of 35 ml/min with a warming temperature of 37 ºC and a warming distance of 100 cm. This unique code will also be used to name the CSV file described above.

3.8.4 Data analysis

Data analysis will be performed in consultation with a statistician and using the latest version of the statistical computing and graphics programme R[35]. All measured temperatures will be summarised and expressed as a mean and a standard deviation assuming a normal distribution. T-tests will be used to compare the temperature readings at T3, T4 and T5 within the Hotline® and the BaRA devices. One-way ANOVA will be used in the comparison of mean temperatures between the three groups and a Bonferroni post-hoc adjustment being applied as necessary. The level of significance will be set at 5%.

3.9 Significance of the study

Scarcity is often a catalyst for innovation and creativity. Often, it is scarcity of financial resources that drives the quest for cheaper solutions to problems. Frugal innovation has recently emerged as a process that matches the resource limitations with an acceptable solution. Weyrauch and Herstatt[26] describe the three criteria for frugal innovation as being a significant cost reduction, concentration on core functionalities and optimised performance level.

The BaRA devices are examples of frugal innovation They are novel IV warming solutions that have emerged due to scarcity of a commercially available alternative. Compared to the Hotline®, approximately R15 000 for the warming unit and R500 for the consumables, these configurations are a fraction of the price. The consumables for a BaRA device will cost R5.75 per 100 cm segment of extension tubing. Both BaRA devices also focus on a core functionality without any emphasis on aesthetics, ergonomics or electronic enhancements such as temperature selection. What is lacking for these devices is an assessment of their performance.

In a resource limited perioperative setting the absence of appropriate fluid warming devices places the patient at risk of receiving cold IV fluids with resultant hypothermia and related morbidities. This study will assess the performance of the BaRA devices and illustrate the effectiveness, or not, of these commonly used devices which are potentially a more cost effective method for warming IV fluids.

3.10 Validity and reliability of the study

According to Heale and Twycross[36], validity and reliability are ways to assess the quality of a quantitative study. Validity refers to appropriateness of a tool to measure a concept while reliability relates the accuracy of the measurement tool in taking the measurement. The example they offer to explain this is an alarm clock set for 07:00 that goes off every morning at exactly 06:30. The alarm clock has a high degree of reliability but its validity is low in this instance[36].

In order to ensure external validity of the study, experimental conditions will be kept as close to those in a clinical setting as possible with special attention being paid to the following factors.

- The ambient operating theatre temperature will be kept constant using the built in hospital air-conditioning system. This temperature will be recorded before each experiment.
- Ringers Lactate and Voluven® will be stored overnight in the theatre where the experiments will take place so that they are at room temperature before being used in the experiments. This will be confirmed using the measurement at T1.
- The PRBC will be collected from SANBS in a cooler box to ensure that they remain refrigerated. The unused units will remain refrigerated until they are needed for the experiments.
- Warming device temperature will be controlled as follows: The BaRA A device relies on a warm water bath, whose temperature will be controlled by the titration of hot water from a boiled kettle. The forced air warmer used in the BaRA B configuration and the Hotline® are electronic and have predetermined temperatures that can be selected.
- The thermistors probes used are highly accurate, with a range of 0.2 ºC , within their operating temperature range (-50 to 250 ºC). The thermistor probes will be calibrated against a laboratory thermometer at the Wits Department of Physiology in order to obtain A, B and C coefficients for use in the Steinhart-Hart equation.
- The flow rate of each cannula will be verified before use. Each fluid will be run through the cannula for a period of one minute and the volume collected in that time will be measured to determine the cannula flow rate. Flow rate is also dependent on the driving

pressure behind the fluid. The fluid bags will be standardised at a height of 1.5m above the warming device to control for this.

- Data collection will occur simultaneously at all temperature points using a digital multichannel thermistor. Two suitably trained assistants will assist the principle investigator with the setup and data capturing during the experiments.
- Data analysis will be performed by a statistician using well known and validated statistical tools.

3.11 Potential limitations of the study

As with any experimental study, a highly controlled environment does not represent everyday clinical practice and so results may not have similar external validity. Commonly available IV tubing and cannula will be used in the experiments in order to mimic real practice. While these consumables will remain constant for the experiments, in everyday practice there are a range of different products available with varying lengths and internal diameters that would be substituted in their place and would affect flow rate and fluid warming characteristics.

The ambient temperature relies on a functional air conditioning system. This is on occasion unreliable with a fluctuation in ambient temperature. The ambient temperature will be recorded before each experiment to track any major fluctuations.

Specifically regarding the BaRA A device, there will be a degree of cooling during the experiment and so T2 will not remain stable. Experiments will be of a short duration and so this cooling effect is not expected to be large. Temperature at T2 will be monitored before the start of the experiment and efforts will be made to ensure this temperature remains in a narrow range for each experiment.

The flow rate will be gravity driven from a height of 1.5 meters from the level of the end of the IV tubing. As the volume of fluid in the storage bag empties there will be a minor reduction in the driving pressure.

3.12 Project outline

The table below describes the estimated timeline for completion of events related to the study. These times are dynamic and in light of the current COVID-19 pandemic are expected to change.

Table 3-1 Project timeline

Activity	March 2020	April 2020	May 2020	June 2020	July 2020	Aug 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2021
Proposal preparation										
Literature review										
Proposal submission										
Ethics approval										
Postgraduate approval										
Data collection										
Data analysis										
Draft article										
Submission										

3.13 Financial plan

The Department of Anaesthesiology will bear the cost of printing and paper for the postgraduate approval. In addition, the department will provide the consumables excluding the blood products for the experiments. The blood products will be supplied by SANBS at no additional cost.

The principal researcher will fund the remainder of the costs as outlined below

Table 3-2 Financial plan

Item	**Dept Anaesthetics**	**Principal Researcher**	**Total**
Printing (Proposal, Post graduate forms, Complete report)	R 150 R 12 R 400		R 150 R 12 R 400
Consumables (IV cannulae and tubing, Voluven®, Ringers Lactate)	R300		R300
Multichannel Thermistor		R650	R650
Calibration		R200	R200
Grand total			**R 1712**

3.14 References

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Section 4. Appendices and Annexures

4.1 Appendix A - Human Research Ethics Approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr K Wilson

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M2008107

NAME: (Principal Investigator)	Dr K Wilson
DEPARTMENT:	School of Clinical Medicine Deparment of Anaesthesiology Medical School University
PROJECT TITLE:	A comparison of the warming capabilities of two Baragwanath Rewarming Appliances with the Hotline Fluid Warming Device
DATE CONSIDERED:	Ad hoc
DECISION:	Approved unconditionally
CONDITIONS:	Laboratory study - no human or animal participants
SUPERVISOR:	Dr M Fourtounas
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2020/09/07

This clearance certificate is valid for 5 years from the date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **September** and will therefore reports and re-certification will be due early in the month of **September** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date

4.2 Appendix B – SANBS Approval

Head Office or Zone
1 Constantia Boulevard
Constantia Kloof Ext 22, 1709

Postal Address: Private Bag X14, Weltevreden Park, 1715
Tel: 011 761 9000 **Email:** customerservice@sanbs.org.za
www.sanbs.org.za

NPO Number: 049066NPO
NPC Registration No. 2000/026390/08

SOUTH AFRICAN NATIONAL BLOOD SERVICE NPC
Human Research Ethics Committee

OHRP Number : IORG0006278
FWA Registration Number : IRB00007553
SA NHREC Registration Number : REC-270606-013

Secretariat: Tel: 011 761 9096 | Valencia.Simmadari@sanbs.org.za

To : Dr Kyle Wilson
E-mail : kyle@rehealthconsulting.com

Dear Dr Wilson,

DATE OF COMMITTEE MEETING : **8th September 2020**
PROJECT TITLE : **A COMPARISON OF THE WARMING CAPABILITIES OF TWO BARAGWANATH REWARMING APPLIANCES WITH THE HOTLINE® FLUID WARMING DEVICE**
DECISION OF THE COMMITTEE : **APPROVED**
CLEARANCE CERTIFICATE NUMBER : **2019/0520**

1. Execution of the study must be compliant with applicable guidelines and policies.
2. Any amendment, extension or any other modifications to the protocol must be submitted to this Ethics Committee for approval prior to implementation.
3. The Committee must be informed of any serious adverse event, planned and unplanned termination of the study.
4. A progress report should be submitted yearly for studies longer than a year and a final report at completion of the study for both short term and long term studies.
5. Kindly refer to the SANBS HREC clearance certificate number on all future correspondence on this study to the HREC secretariat.
6. This approval is valid for 5 years from the date stated above.

COMMITTEE GUIDANCE DOCUMENTS:

- International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Guideline (ICH, 1996), Ethics in Health Research: Principles, Structures and Procedures (SA Department of Health, 2015); Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (SA Department of Health, 2006); Ethical Principles for Medical Research Involving Human: Declaration of Helsinki (World Medical Association, 2013); Reviewing Clinical trials: A Guide For Ethics Committees (Karlberg and Speers, 2010).



CHAIRPERSON: Prof J.N. Mahlangu

17 September 2020
DATE

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Company Secretary: M Luthuli
FBM-CEO-002
1001481 REV 25 (14/08/20)

4.3 Appendix C – Permission Medical Advisory Committee

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 17th June 2020

TITLE OF PROJECT:

A comparison of the warming capabilities of two Baragwanath Rewarming Appliances with the Hotline Fluid warming device.

UNIVERSITY: Witswatersrand

Principal Investigator: Dr K Wilson

Department: Anaesthesiology

Supervisor : Dr M Fourtounas

Permission Head Department (where research conducted): Yes

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Academic Hospital. The CEO / management of Chris Hani Baragwanath Academic Hospital is accordingly informed and the study is subject to:-

- **Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.**
- The Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- The MAC will be informed of any serious adverse events as soon as they occur
- Permission is granted for the duration of the Ethics Committee Approval.

.....
Recommended
(On behalf of the MAC)
Date: 17/06/2020

.....
Approved/~~Not Approved~~
Hospital Management
Date: 25/06/2020

4.4 Appendix D – Permission Heads of Department

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
DIRECTORATE - ANAESTHESIA
Enquiries: Dr P. Mogane
Tel. number: (011) 933-9334
Email: Palesa.Mogane@wits.ac.za

Department of Anaesthesiology
Chris Hani Baragwanath Academic Hospital
PO Bertsham
2013
02 June 2020

To whom it may concern

RE: PERMISSION TO CONDUCT RESEARCH

This serves to confirm that I grant permission for Dr Kyle Wilson to conduct research involving the Department of Anaesthesia at the Chris Hani Baragwanath Academic Hospital. The research topic is titled: A comparison of the warming capabilities of two Baragwanath Rewarming Appliances with the Hotline® Fluid warming device.

I'd like to wish her luck in this endeavor and I am happy to support her wherever possible.

Kind regards.

Dr Palesa Mogane
Chief specialist and Head of Department
Department of Anaesthesiology
Chris Hani Baragwanath Academic Hospital
University of Witwatersrand
Email: Palesa.Mogane@wits.ac.za

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

WITS UNIVERSITY

Department of Anaesthesia – University of the Witwatersrand

7 York Road, Parktown, 2193 South Africa • Telegrams "Witsmed" • Telephone (011) 488-4344 • Fax (011) 488-4343

Department of Anaesthesia
Area 361
Charlotte Maxeke Johannesburg Academic Hospital

Tel: 011 488-4344

2 June 2020

Subject: **Permission to conduct survey from Department of Anaesthesiology**

To whom it may concern,

This letter stands to affirm that I, Dr PMV Motshabi, grant permission to Dr Kyle Wilson HPCSA number MP 0751308, to conduct survey in Department of Anaesthesiology at University of Witwatersrand for his study "A comparison of the warming capabilities of two Baragwanath Rewarming Appliances with the Hotline® Fluid warming device".

The approximate period will be, but not limited to, the months of June 2020 to December 2020, until his sample size is obtained. The information obtained from the data will be used for Dr Wilson research study for his Masters in Medicine only, and will include information and data relevant to his study.

Yours sincerely,

WITS UNIVERSITY

Dr Palesa Motshabi
Academic Head: Department of Anaesthesia
Head of Clinical Unit: Cardiac Anaesthesia

Tel: +27 (0)11 488 4344
Cell: 083 432 1964
Email: palesa.motshabi@wits.ac.za
Website: www.wits.ac.za

WITS SCHOOL OF CLINICAL MEDICINE | FACULTY OF HEALTH SCIENCES

Charlotte Maxeke Johannesburg Academic Hospital, 6th Floor, Room 30419K, Jubilee Road, Parktown, Johannesburg

4.5 Appendix E – Turnitin Report

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4.6 Appendix F – Supplement – Multichannel thermistor and BaRAGRABA 2.0 construction and calibration

This supplement describes the construction and calibration of the multichannel thermistor and data capture application. This process took place in consultation with an independent electrical engineer and the Wits School of Electrical and Information Engineering. Calibration of the device took place at the Wits School of Physiology using a standardised thermometer for reference temperature measurements.

Multichannel Thermistor

The circuit diagram (Figure 4 -1) below describes the construction of the multichannel thermistor used for temperature measurement.

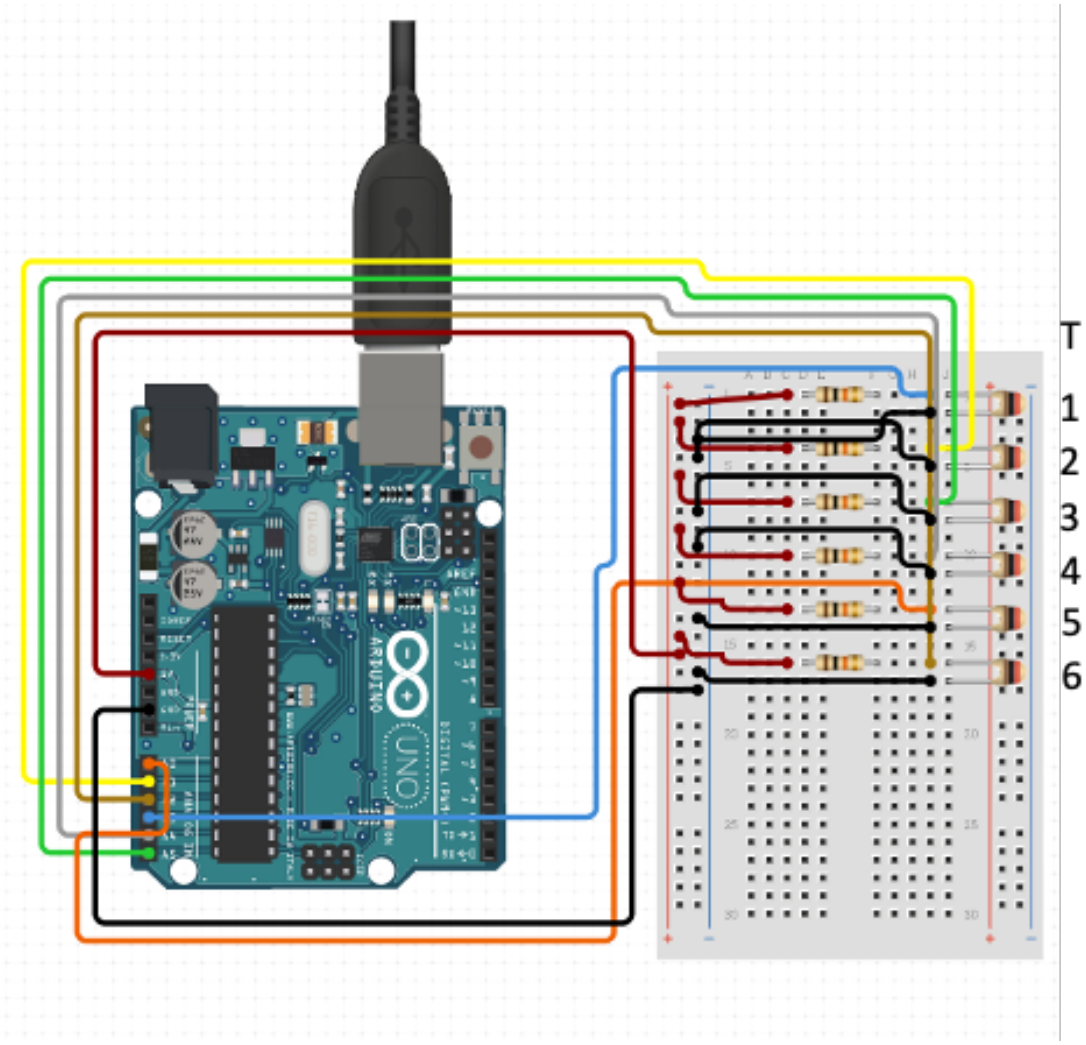


Figure 0-1 Circuit diagram

Table 4.1 lists the components used in the construction of the multichannel thermistor.

Table 0-1 Multichannel thermistor components

Component	Manufacturer/Serial Number	Notes
Microcontroller	Arduino Uno Arduino LLC Inc, 10 St. James Avenue, Boston Massachusetts, 02116, USA	https://www.arduino.cc/
Thermistors	10k ohm glass bead thermistors DHT0B103J3953SY Communica Electronics	6 thermistors used and labelled T1 – T6
Resistors	10k Ohm	

Table 4-2 contains the source code for the microcontroller. Note in line 14 of the microcontroller code the values c1, c2 and c3 correspond to the A,B and C coefficients required for the Steinhart-Hart equation. The code has been modified from the original open source version and is available at www.create.arduino.cc [1].

Table 0-2 Multichannel thermistor source code

```
1.  #include <OneWire.h>
2.  #include <DallasTemperature.h>
3.
4.  #define ONE_WIRE_BUS 5
5.
6.  OneWire oneWire(ONE_WIRE_BUS);
7.
8.  DallasTemperature sensors(&oneWire);
9.
10. float Celcius=0;
11. int sensorPins[] = {A0, A1, A2, A3, A4};
12. float R1 = 10000;
13. float logR2, R2, T;
14. float c1 = 1.753159443e-03, c2 = 0.5683506275e-04, c3 = 18.16478028e-07;
15.
16. void setup() {
17.   Serial.begin(9600);
18.   sensors.begin();
```

```
  Serial.println();
  Serial.println("t6,t5,t4,t3,t2,t1,");
}

float readSensor(int number) {
  float value;
  value = analogRead(number);
  R2 = R1 * (1023 / value - 1);
  logR2 = log(R2);
  T = (1.0 / (c1 + c2 * logR2 + c3 * logR2 * logR2 * logR2));
  T = T - 273.15;
  Serial.print(T);
  Serial.print(",");
  return value;

}

void loop() {
  sensors.requestTemperatures();
  Celcius=sensors.getTempCByIndex(0);
  Serial.print(Celcius);
  Serial.print(",");
  float val;
  for (int i = 4; i >= 0; i--) {
    val = readSensor(sensorPins[i]);

  }
  Serial.println();
  delay(500);
}
```

Figure 4-2 illustrates the modified 3-way Luer stopcock used to record inline fluid temperatures. The thermistor was mounted within the stopcock chamber to minimise interference with fluid flow.

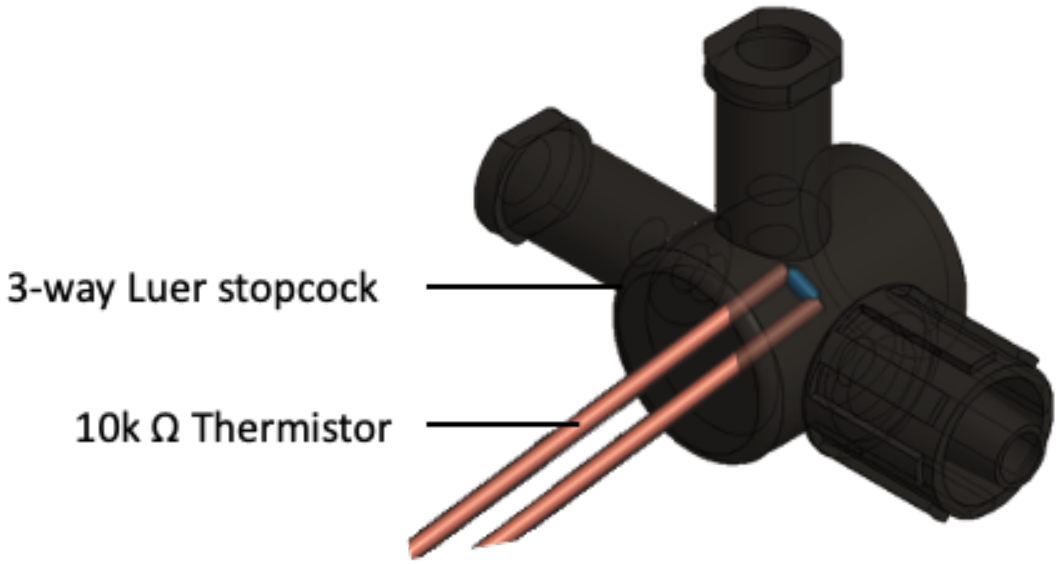


Figure 0-2 Modified Luer stopcock

BaRAGRABA 2.0

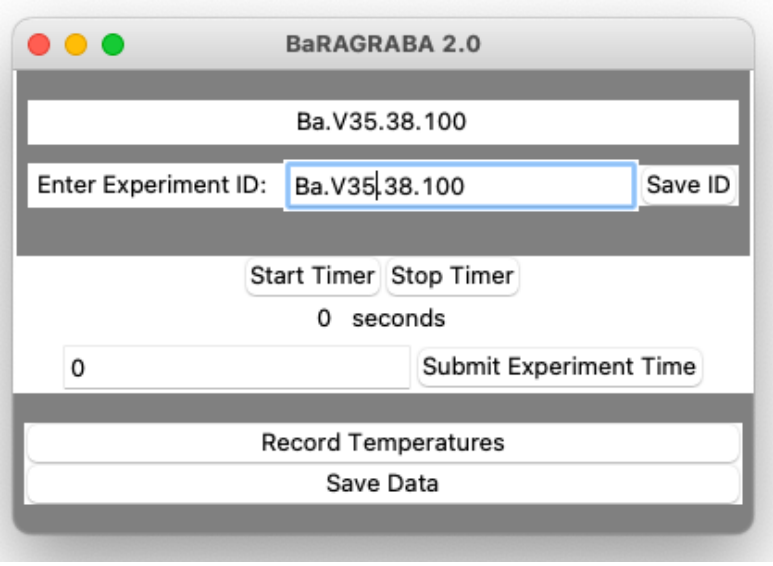


Figure 0-3 BaRAGRABA 2.0

BaRAGRABA 2.0 (Figure 4-3) was designed to read the data transferred from the multichannel thermistor and save it in an appropriate format for further management and interpretation. The application was coded on Python 3.8.2 (v3.8.2:7b3ab5921f, Feb 24 2020, 17:52:18). Table 4-3 contains the source code for this application.

Table 0-3 Source code for BaRAGRABA 2.0

```
import tkinter as tk
import csv
import time
import serial
root = tk.Tk()
root.geometry('400x250')
root.title('BaRAGRABA 2.0')
IDEnterFrame = tk.Frame(root, bg='grey', bd=6,pady=10)
IDEnterFrame.pack()
ExpTimFrame = tk.Frame(root)
ExpTimFrame.pack()
transFrame = tk.Frame(root)
transFrame.pack()
secondtestFrame = tk.Frame(root)
secondtestFrame.pack()
StartExpFrame = tk.Frame(root, bg='grey', bd=6,pady=10)
StartExpFrame.pack(fill=tk.X)
######################ExpIDEnter##############################
# Enters the experiment Identifier. Needs to update the experiment ID so that a csv filename
# is the same as the experiment ID
en = tk.StringVar()
ent = tk.StringVar()
experimentID = ''
def subID():
global experimentID
ent.set(en.get())
experimentID = en.get()
ExperimentNr = tk.Label(IDEnterFrame, textvariable = ent).pack(fill=tk.X)
expLabel = tk.Label(IDEnterFrame, text='Enter Experiment ID: ').pack(side=tk.LEFT)
expEnter = tk.Entry(IDEnterFrame, textvariable=en).pack(side=tk.LEFT,pady=8)
expButt = tk.Button(IDEnterFrame, text='Save ID', command=subID).pack(side=tk.LEFT)
########################ExpTime##############################
# Experiment duration = airbubble transit time from T1-T5 + 5seconds
# The start timer will be pressed when the flow starts and stopped when
# bubble is distal to T5.
# This transit time will be used to calculate the number of items collected
# from the Arduino.
# items collected = transit time(seconds) * 2 (500ms sampling)+ 10 (5s * 2)
d = tk.StringVar()
d.set('0')
dd = 0
starttime = None
def start():
global starttime,dd
if starttime is not None:
d.set(f"Running")
print("timer is running press STOP")
else:
starttime = time.perf_counter()
print(f"TIMER RUNNING @ {starttime:.2f}")
def stop():
'''Stop Timer'''
global starttime,d,dd
if starttime is None:
d.set(f"Stopped")
print("Timer is stopped press start")
dd = (time.perf_counter() - starttime)
d.set(f"{(time.perf_counter() - starttime):.2f}")
print(f"TIMER STOPPED @ {time.perf_counter():.2f}")
starttime = None
print(f"Transit time is: {dd:.2f} seconds")
timStart = tk.Button(ExpTimFrame, text="Start Timer", command=start).pack(side=tk.LEFT)
timStop = tk.Button(ExpTimFrame, text='Stop Timer', command=stop).pack(side=tk.LEFT)
timTransit = tk.Label(transFrame, textvariable = d).pack(side = tk.LEFT)
SecLabel = tk.Label(transFrame, text='seconds').pack(side = tk.LEFT)
##################Enter Transit time for Second TEst##############
# enter prev experiment duration
# will save the time and assign it to variable dd
# dd used to calculate duration of arduino collection
ttime = tk.IntVar()
```

```
71.  def SubTim():
72.  global dd
73.  dd = ttime.get()
74.  timEnter = tk.Entry(secondtestFrame, textvariable = ttime).pack(side = tk.LEFT)
75.  timButton = tk.Button(secondtestFrame, text='Submit Experiment Time', command = SubTim).pack(side = tk.LEFT)
76.  ##################StartExp##############################
77.  # Recording of temperature begins with this button.
78.  # 2 functions are possible. Firstly RArduino() collects information
79.  # from the Arduino. The number of items collected are calculated from
80.  # the transit time as explained in ExpTime above
81.  # The second function saves the data as a csv with filename entered in
82.  # ExpIDEnter. It then clears the data[] list and the input fields on the BaRAGRABA app and
83.  # prepares for a new experiment.
84.  data = []
85.  def RArduino():
86.  global data, ser, experimentID, dd
87.  e = ent.get()
88.  experimentID = e
89.  duration = (dd*(1/0.5)+10)
90.  ser = serial.Serial('/dev/tty.usbmodem14101', 9600)
91.
92.  for i in range (int(duration)):
93.  b = ser.readline()
94.  serial_n = b.decode()
95.  string = serial_n.rstrip()
96.  data.append(string)
97.  time.sleep(0)
98.
99.  ser.close()
100. print("FINISHED READING")
101. print(data)
102. print(len(data))
103. time.sleep(1)
104. print("Reminder: Review Data and Save")
105. def P2CSV():
106. global data, experimentID, d
107. print("Saving Data for experiment nr: ", experimentID)
108. with open('%s.csv' %(experimentID), 'w', newline='') as f:
109. for i in data:
110. writer = csv.writer(f)
111. writer.writerow([i])
112. data.clear()
113. strd = str(dd)
114. with open('testime', 'a', newline = '') as t:
115. t.write(f'{experimentID} -----  {strd} \n')
116. time.sleep(2)
117. print("DONE saving experiment nr: ", experimentID)
118. d.set(0)
119. en.set('')
120. ent.set('')
121. expStart = tk.Button(StartExpFrame, text='Record Temperatures', command=RArduino).pack(fill=tk.X)
122. saveExp = tk.Button(StartExpFrame, text='Save Data', command=P2CSV).pack(fill=tk.X)
123. root.update_idletasks()
124. root.mainloop(
```

Multichannel thermistor calibration

The multichannel thermistor was calibrated against the Bat-12 Microprobe Thermometer (Physitemp Instruments INC, 154 Huron Avenue, Clifton, NJ 07013, USA). The calibration took place at the Wits University School of Physiology teaching laboratory. The temperature, as measured by the BAT-12, and corresponding resistance of the thermistors were measured at three different temperatures. These temperatures were selected from the expected temperature range of the experiments and represent the lower (0 ºC) the mid-point (27 ºC) and the upper limit (50 ºC) of the temperature range. These temperature-resistance pairs were entered into the SRS Thermistor Calculator (Stanford Research Systems, available at https://www.thinksrs.com/downloads/programs/therm%20calc/ntccalibrator/ntccalculator.html). A, B and C coefficients calculated by the SRS Calculator were entered into the Steinhart-Hart equation in line 14 of the multichannel thermistor source code, and correlate with c1, c2 and c3. Figure 4-4 shows the results of this calibration

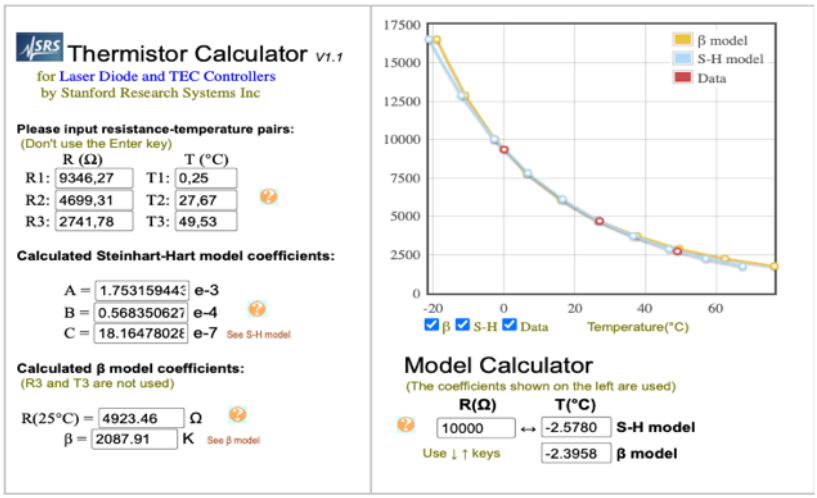


Figure 0-4 Calibration calculation

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